

ECF CASE

JUDGE SWAIN

Porter F. Fleming (PF-1510)  
James K. Stronski (JS-4883)  
FROMMER LAWRENCE & HAUG LLP  
745 Fifth Avenue  
New York, NY 10151  
(212) 588-0800

04 CV 3627

UNITES STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

NOVOGEN RESEARCH PTY. LTD.,

Plaintiff,

v.

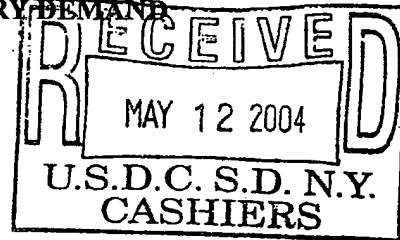
GENERAL NUTRITION CENTERS, INC.,

Defendant.

Civil Action No.

COMPLAINT

JURY DEMAND



Plaintiff Novogen Research Pty. Ltd. ("Novogen") for its Complaint against defendant General Nutrition Centers, Inc. ("GNC") avers and alleges as follows:

JURISDICTION AND PARTIES

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271 *et. seq.*
2. Jurisdiction and venue are proper in this Judicial District pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, 1400(b) and N.Y. Civ. Prac. L & R 302(a).
3. Plaintiff Novogen is an Australian corporation having its principal place of business in New South Wales, Australia.
4. Defendant GNC is, on information and belief, a Delaware corporation having offices in Pittsburgh, PA and is committing acts of patent infringement in this Judicial District.

Upon information and belief, defendant GNC transacts business generally in this Judicial District.

**CAUSE OF ACTION FOR PATENT INFRINGEMENT  
OF UNITED STATES PATENT NO. 6,562,380**

5. On May 13, 2003, United States Letters Patent No. 6,562,380 ("the '380 patent") entitled "Methods for Treating or Reducing Pre-Disposition to Breast Cancer, Pre-Menstrual Syndrome or Symptoms Associates With Menopause By Administration of Phyto-Estrogen", was duly and legally issued to Graham Edmund Kelly. A true and correct copy of the '380 patent is attached to this Complaint as Exhibit A.

6. Plaintiff Novogen Research Pty. Ltd. is the owner and assignee of the '380 patent with rights to enforce the '380 patent.

7. Defendant GNC has been on notice of the approval by the U.S. Patent and Trademark Office of patent claims covering, among other things, the treatment of menopausal symptoms using certain isoflavones — which subsequently issued as the '380 patent on May 13, 2003 — at least as early as correspondence dated on or about January 30, 2002.

8. Defendant GNC has been on notice of the existence and has had actual knowledge of the '380 patent at least as early as correspondence dated on or about June 6, 2003.

9. Defendant GNC has committed acts of infringement of said '380 patent in this Judicial District and elsewhere by selling products that are used for the patented method and by inducing and contributing to the use of the patented method without authority or license from plaintiff. Upon information and belief, such acts of infringement by defendant have been willful.

10. Plaintiff has suffered and will continue to suffer damages and irreparable injury as a result of defendant GNC's infringement unless enjoined by this Court.

### **REQUEST FOR RELIEF**

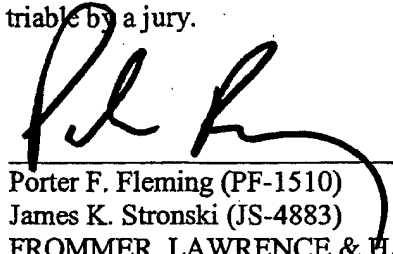
Wherefore, plaintiff prays for judgment:

11. That defendant GNC has infringed the '380 patent.
12. That defendant GNC's infringement of the '380 patent is willful.
13. Ordering that defendant, its officers, subsidiaries, agents, servants, employees and attorneys, and all persons in active concert or participation with any of them, be preliminary and permanently enjoined and restrained from any further infringement of United States Letters Patent No. 6,562,380.
14. Awarding plaintiff Novogen its damages caused by Defendant GNC, and that such damages be trebled.
15. Awarding plaintiff interest, costs and disbursements in this action, including reasonable attorney's fees pursuant to 35 U.S.C. § 285; and
16. Awarding plaintiff such further relief as the Court may deem just and proper.

**JURY DEMAND**

17. Plaintiff requests a jury for all issues triable by a jury.

Dated: New York, New York  
May 12, 2004



---

Porter F. Fleming (PF-1510)  
James K. Stronski (JS-4883)  
FROMMER, LAWRENCE & HAUG LLP  
745 Fifth Avenue  
New York, New York 10151  
(212) 588-0800

Attorneys for Plaintiff  
Novogen Research Pty. Ltd.

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

ECF CASE

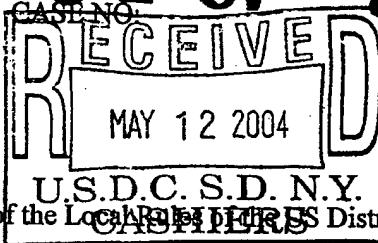
JUDGE SWAIN

NOVOGEN RESEARCH PTY. LTD,  
Plaintiff,

v.

GENERAL NUTRITION CENTERS, INC.  
Defendant.

RULE 7.1 STATEMENT



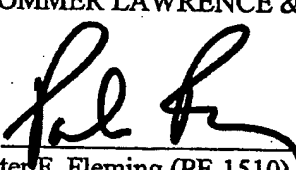
Pursuant to Rule Fed.R.Civ.P. 7.1 (formerly Local Rule 9 of the Local Rules of the District

Court for the Southern and Eastern Districts of New York and to enable Judges and Magistrate  
Judges of the Court to evaluate possible disqualifications or recusal), the undersigned counsel for  
Novogen Research PTY. LTD. (a private non-governmental party) certifies that the following are  
corporate parents, affiliates ad/or subsidiaries of said party which are publicly held:

Novogen Limited (ADR traded as NVGN)  
Marshall Edwards, Inc. (variously trades as MSH or MSHL or MSHLW)

Dated: May 12, 2004.

FROMMER LAWRENCE & HAUG LLP

By:   
Porter F. Fleming (PF-1510)  
James K. Stronski (JS-4883)  
745 Fifth Avenue  
New York, NY 10151  
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Porter F. Fleming (PF-1510)  
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745 Fifth Avenue  
New York, New York 10151  
(212) 588-0800

**UNITES STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

-----X  
**NOVOGEN RESEARCH PTY. LTD.,**

**Plaintiff,**

**v.**

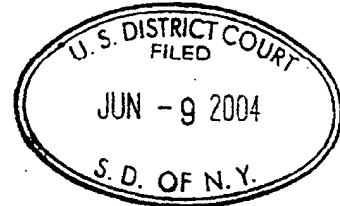
**GENERAL NUTRITION CENTERS, INC.,**

**Defendant.**  
-----X

**Civil Action No.**

**FIRST AMENDED COMPLAINT**

**JURY DEMAND**



Plaintiff Novogen Research Pty. Ltd. ("Novogen") for its First Amended Complaint  
against defendant General Nutrition Centers, Inc. ("GNC") avers and alleges as follows:

**JURISDICTION AND PARTIES**

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271 *et. seq.*
2. Jurisdiction and venue are proper in this Judicial District pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, 1400(b) and N.Y. Civ. Prac. L & R 302(a).
3. Plaintiff Novogen is an Australian corporation having its principal place of business in New South Wales, Australia.
4. Defendant GNC is, on information and belief, a Delaware corporation having offices in Pittsburgh, PA and is committing acts of patent infringement in this Judicial District.

Upon information and belief, defendant GNC transacts business generally in this Judicial District.

**CAUSE OF ACTION FOR PATENT INFRINGEMENT  
OF UNITED STATES PATENT NO. 6,562,380**

5. On May 13, 2003, United States Letters Patent No. 6,562,380 ("the '380 patent") entitled "Methods for Treating or Reducing Pre-Disposition to Breast Cancer, Pre-Menstrual Syndrome or Symptoms Associated With Menopause By Administration of Phyto-Estrogen", was duly and legally issued to Graham Edmund Kelly. A true and correct copy of the '380 patent is attached to this Complaint as Exhibit A.

6. Plaintiff Novogen Research Pty. Ltd. is the owner and assignee of the '380 patent with rights to enforce the '380 patent.

7. Defendant GNC has been on notice of the approval by the U.S. Patent and Trademark Office of patent claims covering, among other things, the treatment of menopausal symptoms using certain isoflavones — which subsequently issued as the '380 patent on May 13, 2003 — at least as early as correspondence dated on or about January 30, 2002.

8. Defendant GNC has been on notice of the existence and has had actual knowledge of the '380 patent at least as early as correspondence dated on or about June 6, 2003.

9. Defendant GNC has committed acts of infringement of said '380 patent in this Judicial District and elsewhere by selling products containing certain phytoestrogens from clover that are used for the patented method and by inducing and contributing to the use of the patented method without authority or license from plaintiff. Upon information and belief, such acts of infringement by defendant have been willful.

10. Plaintiff has suffered and will continue to suffer damages and irreparable injury as a result of defendant GNC's infringement unless enjoined by this Court.

**REQUEST FOR RELIEF**

Wherefore, plaintiff prays for judgment:

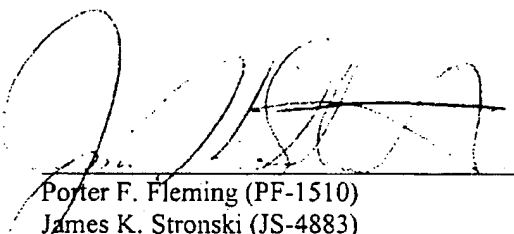
11. That defendant GNC has infringed the '380 patent.
12. That defendant GNC's infringement of the '380 patent is willful.
13. Ordering that defendant, its officers, subsidiaries, agents, servants, employees and attorneys, and all persons in active concert or participation with any of them, be preliminary and permanently enjoined and restrained from any further infringement of United States Letters Patent No. 6,562,380.
14. Awarding plaintiff Novogen its damages caused by Defendant GNC, and that such damages be trebled.
15. Awarding plaintiff interest, costs and disbursements in this action, including reasonable attorney's fees pursuant to 35 U.S.C. § 285; and
16. Awarding plaintiff such further relief as the Court may deem just and proper.



**JURY DEMAND**

17. Plaintiff requests a jury for all issues triable by a jury.

Dated: New York, New York  
June 9, 2004



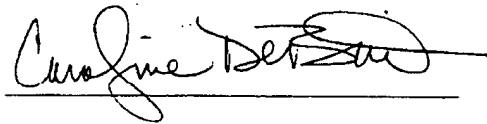
Porter F. Fleming (PF-1510)  
James K. Stronski (JS-4883)  
FROMMER, LAWRENCE & HAUG LLP  
745 Fifth Avenue  
New York, New York 10151  
(212) 588-0800

Attorneys for Plaintiff  
Novogen Research Pty. Ltd.

**CERTIFICATE OF SERVICE**

I hereby certify that on this 9th day of June 2004, a copy of the foregoing AMENDED COMPLAINT was served by Facsimile and Federal Express on:

Joseph Melnik  
Pepper Hamilton LLP  
50th Floor, One Mellon Bank Center  
500 Grant Street  
Pittsburgh, PA 15219  
412-454-5812  
412-281-0717 (fax)

A handwritten signature in dark ink, appearing to read "Caroline Detsch", is written over a horizontal line.

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

NOVOGEN RESEARCH PTY. LTD.,

Plaintiff

v.

GENERAL NUTRITION CENTERS, INC.

Defendant

CIVIL ACTION NO.: 04-CV-3627 (LTS)  
(DFE)

JURY TRIAL DEMANDED

**ANSWER, AFFIRMATIVE DEFENSES, AND  
COUNTERCLAIMS TO FIRST AMENDED COMPLAINT**

NOW COMES Defendant, General Nutrition Centers, Inc. ("GNC"), by their undersigned counsel, and responds to the allegations in the numbered paragraphs of the First Amended Complaint filed by Plaintiff, Novogen Research Pty. Ltd. ("Novogen"), as follows:

**GENERAL DENIAL**

Except as hereinafter expressly admitted, GNC denies each and every allegation set forth in the Complaint.

**SPECIFIC RESPONSES**

**JURISDICTION AND PARTIES**

1. GNC admits that the First Amended Complaint purports to state a claim for patent infringement pursuant to 35 U.S.C. § 271 *et seq.*
2. GNC admits that jurisdiction and venue are proper in this Judicial District.
3. GNC does not have sufficient information to either admit or deny the allegations contained in paragraph three of the First Amended Complaint and, therefore, they are denied.

4. GNC admits it is a Delaware corporation having offices in Pittsburgh, Pennsylvania and it transacts business generally in this Judicial District. GNC denies the remaining allegations set forth in paragraph four of the First Amended Complaint.

**CAUSE OF ACTION FOR PATENT INFRINGEMENT OF UNITED STATES PATENT  
NO. 6,562,380**

5. GNC does not have sufficient information to either admit or deny whether the '380 patent was duly and legally issued to Graham Edmund Kelley or whether a true and correct copy of the '380 patent is attached as Exhibit A to the First Amended Complaint. With respect to the remaining allegations of Paragraph 5 of the First Amended Complaint, GNC states that the document speaks for itself.

6. GNC does not have sufficient information to either admit or deny the allegations contained in paragraph six of the First Amended Complaint and, therefore, they are denied.

7. GNC does not have sufficient information to either admit or deny the allegations contained in paragraph seven of the First Amended Complaint and, therefore, they are denied.

8. GNC does not have sufficient information to either admit or deny the allegations contained in paragraph eight of the First Amended Complaint and, therefore, they are denied.

9. GNC denies the allegations set forth in paragraph nine of the First Amended Complaint.

10. GNC denies the allegations set forth in paragraph ten of the First Amended Complaint.

### **FIRST AFFIRMATIVE DEFENSE**

Plaintiff's First Amended Complaint fails to state any claim against Defendant upon which relief can be granted.

### **SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims and/or alleged damages are barred in whole or in part by the doctrine of laches.

### **THIRD AFFIRMATIVE DEFENSE**

Plaintiff's claims and/or alleged damages are barred in whole or in part by the doctrine of estoppel.

### **FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims and/or alleged damages are barred in whole or in part by the doctrine of unclean hands.

### **FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims and/or alleged damages are barred in whole or in part because GNC has a valid and enforceable license to each of the claims of U.S. Patent No. 6,562,380.

### **SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's claims and/or alleged damages are barred in whole or in part by the statute of limitations.

### **SEVENTH AFFIRMATIVE DEFENSE**

Each claim of the '380 patent is invalid for non-compliance with the rules and regulations of the U.S. Patent Office and for non-compliance with the Patent Act, 35 U.S.C. § 101 et seq., including but not limited to, under 35 U.S.C. § 102 as lacking novelty, is invalid under 35 U.S.C. § 103 because the differences between the subject matter claimed and the prior art are such that it would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which the subject matter pertains; and/or is invalid for failure to comply with the requirements of 35 U.S.C. § 112.

#### **EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff has failed to join necessary and indispensable parties to this litigation.

WHEREFORE, GNC respectfully requests that this Court dismiss Plaintiff's First Amended Complaint with prejudice and award to GNC its costs and attorneys' fees in defending against this First Amended Complaint as well as such other and further relief as is just and proper.

#### **COUNTER-CLAIM**

Defendant, GNC, submits this counterclaim pursuant to Rule 13 of the Federal Rules of Civil Procedure and, in support thereof, states and avers as follows:

#### **COUNT I** **DECLARATORY JUDGMENT FOR NON-INFRINGEMENT OF THE '380 PATENT**

1. On information and belief, Novogen is an Australian corporation having its principal place of business in New South Wales, Australia.
2. GNC is a corporation organized under the laws of the state of Delaware with its principal place of business located at 300 Sixth Avenue, 3rd Floor, Pittsburgh, PA 15222.
3. This is an action for declaratory judgment of non-infringement of U.S. Patent No. 6,562,380 (the "'380 Patent") pursuant to 28 U.S.C. §2201, et seq.
4. Exclusive jurisdiction over these counterclaims is conferred upon this Court pursuant to 28 U.S.C. § 1338(a).
5. On June 9, 2004, Plaintiff filed a First Amended Complaint against GNC alleging, *inter alia*, that certain products sold by GNC infringe the '380 Patent.

6. A true and actual controversy exists regarding the infringement of the '380 Patent asserted by Plaintiff Novogen against Defendant GNC.

7. None of the products described in the First Amended Complaint infringe the '380 patent. GNC respectfully requests a declaratory judgment pursuant to 28 U.S.C. §2201 et seq. that the products described in the First Amended Complaint are free of infringement of the '380 patent.

**COUNT II**  
**INVALIDITY OF THE '380 PATENT**

8. GNC realleges the allegations set forth above in counterclaim paragraphs 1-7.

9. Each claim of the '380 patent is invalid for non-compliance with the rules and regulations of the U.S. Patent office and/or for non-compliance with the Patent Act, 35 U.S.C. §101 et seq., including but not limited to under 35 U.S.C. § 102 as lacking novelty, is invalid under 35 U.S.C. § 103 because the differences between the subject matter claimed and the prior art are such that it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains; and/or is invalid for failure to comply with the requirements of 35 U.S.C. § 112.

10. GNC respectfully request a declaratory judgment that each and every claim of the '380 patent is invalid.

**PRAYER FOR RELIEF**

WHEREFORE, counterclaim Plaintiff GNC respectfully requests that this Court:

- A. Dismiss Plaintiff's First Amended Complaint with prejudice.
- B. Enter judgment declaring that U.S. Patent No. 6,562,380 is invalid.

C. Enter judgment declaring that GNC does not infringe, nor has it ever infringed, U.S. Patent No. 6,562,380.

D. Enter judgment pursuant to 35 U.S.C. § 285 awarding GNC all of its reasonable attorney fees, costs and expenses incurred in defending this action because this is an exceptional case.

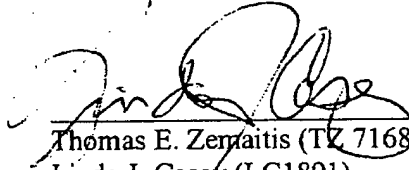
E. Award such other and further relief as may be just and proper under the circumstances.

**DEMAND FOR JURY TRIAL**

GNC demands a trial by jury of all issues so triable as a matter of right.

Respectfully submitted,

Date: August 16, 2004

  
Thomas E. Zernaitis (TZ 7168)

Linda J. Casey (LC1891)

PEPPER HAMILTON LLP

3000 Two Logan Square

18th and Arch Streets

Philadelphia, PA 19103-2799

(215) 981-4361

- and -

1180 Avenue of the Americas, 14<sup>th</sup> floor

New York, NY 10036-8401

(212) 899-5090

- and -

W. Joseph Melnik (*Pro Hac Vice*)

Raymond A. Miller (*Pro Hac Vice*)

PEPPER HAMILTON LLP

500 Grant Street, 50<sup>th</sup> Floor

Pittsburgh, PA 15219

(412) 454-5812

Attorneys for Defendant

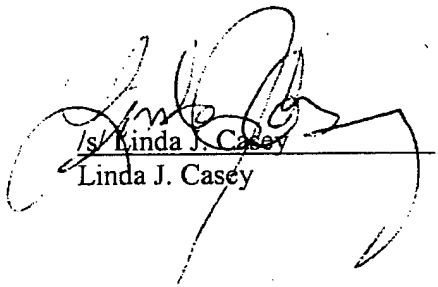
GENERAL NUTRITION CENTERS, INC.



**CERTIFICATE OF SERVICE**

I certify that on this 16<sup>th</sup> day of August 2004, a true and correct copy of the foregoing ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO FIRST AMENDED COMPLAINT was served via first class U.S. mail, postage prepaid, upon the following:

Porter F. Fleming, Esquire  
FROMMER LAWRENCE & HAUG LLP  
745 Fifth Avenue  
New York, NY 10151



/s/ Linda J. Casey  
Linda J. Casey

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

NOVOGEN RESEARCH PTY. LTD.,

04-CV-3627 (LTS)(DFE)

Plaintiff,

vs.

GENERAL NUTRITION CENTERS, INC.

**RULE 7.1 CORPORATE  
DISCLOSURE STATEMENT**

Defendant.

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Defendant General Nutrition Centers, Inc., through its undersigned attorneys, hereby submits its Corporate Disclosure Statement in compliance with the provisions of Rule 7.1, Federal Rules of Civil Procedure.

Defendant declares as follows:

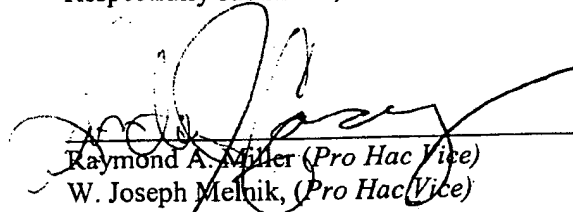
1. Defendant is a subsidiary of GNC Corporation.
2. GNC Corporation is the ultimate parent entity.

Neither entity is publicly traded. A supplemental Corporate Disclosure Statement will be filed upon any change in the information provided herein.

RESPECTFULLY SUBMITTED this 19<sup>th</sup> day of August, 2004.

Dated: August 19, 2004

Respectfully submitted,



Raymond A. Miller (*Pro Hac Vice*)  
W. Joseph Melnik, (*Pro Hac Vice*)

PEPPER HAMILTON LLP  
500 Grant Street, 50<sup>th</sup> Floor  
Pittsburgh, PA 15219  
(412) 454-5812

Thomas E. Zemaitis (TZ 7168)  
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3000 Two Logan Square  
18th and Arch Streets  
Philadelphia, PA 19103-2799  
(215) 981-4361

Attorneys for Defendant  
GENERAL NUTRITION CENTERS, INC.

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X  
NOVOGEN RESEARCH PTY. LTD., :  
 :  
Plaintiff, : Civil Action No. 04 CV 3627 (LTS)  
v. :  
 :  
GENERAL NUTRITION CENTERS, INC., :  
 :  
Defendant. :  
-----X

**PRELIMINARY PRE-TRIAL STATEMENT**

Plaintiff Novogen Research Pty. Ltd. ("Novogen") and Defendant General Nutrition Centers, Inc. ("GNC") submit this Preliminary Pre-Trial Statement pursuant to the Court's May 24, 2004 Order.

**1. Nature of the Action**

This is an action for patent infringement. Novogen alleges that it is the owner and assignee of U.S. Patent No. 6,562,380 ("the '380 Patent") entitled "Methods for Treating or Reducing Pre-Disposition to Breast Cancer, Pre-Menstrual Syndrome or Symptoms Associated With Menopause By Administration of Phyto-Estrogen." The '380 Patent issued on May 13, 2003.

Novogen's Complaint alleges that GNC has and continues to infringe one or more claims of the '380 patent. Novogen seeks a ruling that: (i) GNC has infringed the '380 patent by selling products containing certain phytoestrogens from clover that are used for the patented method under 35 U.S.C. § 271(a); (ii) GNC has induced and contributed to the use of the patented method without authority or license from Novogen under 35 U.S.C. §271(b) and (c) respectively;

(iii) GNC's infringement of the '380 patent was willful; and (iv) GNC be preliminary and permanently enjoined from any further infringement of the '380 patent. Novogen also seeks damages caused by GNC, and that such damages be trebled. Novogen further seeks interest, costs and disbursements in this action, including reasonable attorneys fees.

In its answer, GNC denies that it has infringed the '380 Patent, denies that any alleged infringement was willful, and denies that it has been on notice of the approval or existence of the '380 Patent. GNC has alleged that the '380 Patent is invalid under 35 U.S.C. §§ 102, 103, and 112. GNC seeks a ruling that (i) the products sold and marketed by GNC do not infringe the '380 Patent and (ii) the '380 Patent is invalid under 35 U.S.C. §§ 102, 103, and 112.

## **2. Jurisdiction and Venue**

Jurisdiction and venue are proper in this Judicial District pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, 1400(b) and N.Y. Civ. Prac. L & R 302(a). The parties agree that the Court has subject matter jurisdiction over this action and that the Court has personal jurisdiction over both Novogen and GNC. Novogen is an Australian corporation having its principal place of business in New South Wales, Australia. GNC is a Delaware corporation having offices in Pittsburgh, PA. GNC markets and sells products that are alleged to infringe the '380 patent in this Judicial District.

## **3. Material Uncontested and Admitted Facts**

The issues that are not in dispute include at least the following: (i) The '380 patent was filed on August 13, 1997 and issued on May 13, 2003; and (ii) The '380 patent contains 23 claims, seven of those claims being independent.

## **4. Uncontested Legal Issues**

Claim construction is a matter to be decided by the court. Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996).

A determination of patent infringement requires a two-step process. The court must first construe the claims' scope and meaning, and then the jury must compare the properly construed claims to the allegedly infringing device. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998). To prove infringement, the patentee must show that the accused device meets each claim limitation, either literally or under the doctrine of equivalents. Deering Precision Instruments., L.L.C. v. Vector Distrib. Sys., Inc., 347 F.3d 1314, 1324 (Fed. Cir. 2003), cert. denied, 124 S. Ct. 1426 (2004); see also Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1367 (Fed. Cir. 2004).

Much like infringement, a determination of invalidity requires a two-step process. First the court must construe the claim and second, in the case of anticipation or obviousness, then the fact finder must compare the construed claim(s) to the prior art. See Key Pharm., Inc. v. Hercon Lab., Corp., 161 F.3d 709 (Fed. Cir. 1998). The '380 patent is presumed to be valid. 35 U.S.C. § 282.

##### **5. Legal Issues in Dispute**

The legal issues in dispute are: (1) Novogen's claim that GNC has and continues to infringe the '380 patent; (2) Novogen's claim that GNC has been on notice of the approval of claims covering menopausal symptoms and of the existence and actual knowledge of the '380 Patent; (3) Novogen's claim that GNC's infringement has been willful; (4) GNC's claim that it has sublicensed rights from Solae, LLC under the '380 patent; and (5) GNC's claim that the '380 patent is invalid. To resolve the issues of patent infringement and validity, the court must construe the patent's claims. Typically, this involves briefing by the parties followed by a Markman Hearing.

**6. Material Disputed Facts**

Novogen: Novogen states that the material disputed facts include at least the following (i) GNC's products infringe properly construed claims of the '380 patent; (ii) GNC has sold and continues to sell products that contain phytoestrogen extracted from clover for the treatment of menopausal symptoms (iii) GNC's infringement of the '380 patent has been willful; (iv) Novogen has licensed certain rights to the '380 patent to Solae, LLC; (v) GNC has sublicensed only the soy derived isoflavone rights for menopausal symptoms from Solae, LLC under the '380 patent; (vi) GNC has been on notice of the approval by the U.S. Patent and Trademark Office of patent claims covering, among other things, the treatment of menopausal symptoms using certain isoflavones at least as early as correspondence dated on or about January 30, 2002; (vii) GNC has been on notice of the existence and has had actual knowledge of the '380 patent at least as early as correspondence dated on or about June 6, 2003; and (viii) the amount of damages due Novogen to compensate for past and present infringement of the '380 patent.

GNC: GNC states that the material disputed facts include at least the following: (i) GNC's products do not infringe properly construed claims of the '380 patent; (ii) to the extent any of GNC's products fall within the scope of the properly construed claims of the '380 Patent, such products are authorized and non-infringing pursuant to a license to the '380 Patent that GNC has received from Solae, LLC; (iii) Novogen did not properly put GNC on notice of the approval by the U.S. Patent and Trademark Office of patent claims covering, among other things, the treatment of menopausal symptoms using certain isoflavones, and if Novogen properly put GNC on notice, when were such requirements satisfied; (iv) Novogen did not properly put GNC on notice nor did GNC have actual knowledge of the '380 patent, and if so, when such notice or knowledge was satisfied; and (v) the existence of prior art and other defects and deficiencies in the '380 Patent which invalidate the claims of the '380 Patent.

**7. Legal Basis for Each Cause of Action Asserted**

Novogen: The legal basis for Novogen's infringement claim is at least 35 U.S.C. § 271(a), (b) and (c). Novogen is also entitled to its damages and legal fees under 35 U.S.C. §§ 284 and 285.

GNC: GNC's counterclaims are for a declaratory judgment, pursuant to 28 U.S.C. § 2201, of non-infringement of the '380 Patent, and invalidity of the '380 Patent pursuant to at least 35 U.S.C. §§ 102, 103 and 112. GNC is also entitled to its costs and fees in defending this action pursuant to 35 U.S.C. §285.

**8. Legal Basis for Each Asserted Defense or Expected Asserted Defense**

Novogen: Novogen will deny GNC's counterclaims that the '380 patent is invalid and not infringed. Novogen may also raise additional defenses. The '380 patent is presumed valid under 35 U.S.C. § 282.

GNC: The first through sixth affirmative defenses are equitable and legal defenses based upon GNC's lack of products or conduct which infringes the '380 Patent and Novogen's attempt to enforce against GNC patent claims which are already licensed to GNC. The seventh affirmative defense is that the '380 Patent is invalid for non-compliance with the rules and regulations of the U.S. Patent Office and at least 35 U.S.C. §§ 102, 103 and 112. The eighth affirmative defense is for failure to join necessary and indispensable parties pursuant to Fed. R.Civ.P. Rule 19.

**9. Burden of Proof**

Novogen: The legal standard by which Novogen must prove infringement is by a preponderance of the evidence. SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306, 1325 (Fed. Cir. 2004) (citing S. Bravo Sys., Inc., v. Containment Techs. Corp., 96 F.3d 1372, 1376 (Fed. Cir. 1996)). The legal standard by which Novogen must prove willful infringement is



by clear and convincing evidence. Comark Communs., Inc. v. Harris Corp., 156 F.3d 1182, 1190 (Fed. Cir 1998).

GNC: The legal standard by which GNC must prove invalidity is by clear and convincing evidence. University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920 (Fed. Cir. 2004) (citing U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1563 (Fed. Cir. 1997)).

#### 10. Amendment of Pleadings and Joinder of Parties

The parties propose that any amendments to the pleadings, without leave of Court, must be filed and served by October 1, 2004. The parties also propose that joinder of all parties occur by October 1, 2004.

#### 11. Trial by a Magistrate Judge

The parties do not consent to trial of the case by a magistrate judge.

#### 12. Changes to Disclosures Under Fed. R. Civ. P. 26(a)

The parties do not presently contemplate any changes in the timing, form or requirements for disclosures under Fed. R. Civ. P. 26(a). The parties will exchange Rule 26(a)(1) disclosures by September 20, 2004.

#### 13. Discovery

The parties propose the following pretrial schedule:

Event	Novogen Proposal	GNC Proposal
<b>Fact Discovery</b>		
Exchange of Initial Disclosures	Sept. 20, 2004	
Filing of Amended Pleadings w/o Leave of Court	Oct. 1, 2004	Oct. 1, 2004
Completion of Joinder of Additional Parties	Oct. 1, 2004	Oct. 1, 2004
Service of All Interrogatories and Requests to Admit	on or before Dec. 15, 2004	on or before March 18, 2005
Completion of Fact Discovery	Feb. 28, 2005	May 31, 2005
<b>Markman Proceedings</b>		
Exchange of Opening Claim Construction Briefs	April 11, 2005	Nov. 1, 2004
Exchange of Answering Claim Construction Briefs	May 2, 2005	Nov. 22, 2004
Exchange of Reply Claim Construction Briefs	May 16, 2005	Dec. 13, 2004

<b>Event</b>	<b>Novogen Proposal</b>	<b>GNC Proposal</b>
Markman Hearing	June 1, 2005	Jan. 17, 2005
<b>Expert Discovery</b>		
Opening Expert Reports (burden of proof)	July 1, 2005	July 1, 2005
Answering Expert Reports	July, 18, 2005	July 18, 2005
Completion of Expert Depositions	August 26, 2005	August 26, 2005
<b>Dispositive Motions</b>		
Opening Briefs	on or before Sept. 12, 2005	on or before Sept. 12, 2005
Answering Briefs	within 45 days of filing motion	within 45 days of filing motion
Reply Briefs	within 15 days of Brief in Opposition	within 15 days of Brief in Opposition
<b>Trial Phase</b>		
Pretrial order		
Pretrial conference		
Trial		

#### **14. Expert Evidence**

Expert evidence may be required. The proposed deadlines for expert discovery are detailed above.

#### **15. Limitations of Discovery**

Novogen proposes that at this time the parties adhere to the limitations on discovery set forth in the Federal Rules of Civil Procedure, including: limiting the number of depositions to ten pursuant to Rule 30(a)(2)(A); limiting the length of a deposition to one day of seven hours pursuant to Rule 30(d)(2); and limiting the number of interrogatories to 25 including all discrete subparts pursuant to Rule 33(a).

#### **16. Settlement**

The parties have engaged in settlement discussions. These discussions are ongoing.

#### **17. Jury Trial**

Both parties have requested a jury. The parties estimate a one week trial.

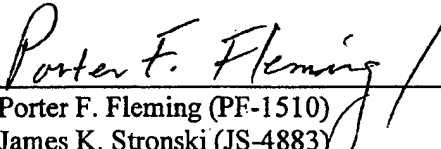
**18. Other Matters**

The parties will meet and confer to prepare a joint protective order for the Court's consideration. The parties do not contemplate any other orders at this time.

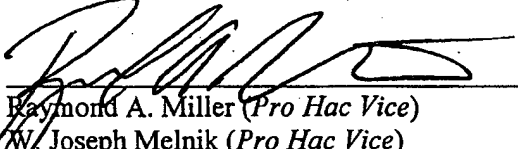
Should the Court have any questions regarding the information and proposals set forth above, counsel for both parties are available to provide additional information as needed.

Dated: August 19, 2004

Respectfully Submitted,

  
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*Attorneys for Defendant  
General Nutrition Centers, Inc.*

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

NOVOGEN RESEARCH PTY. LTD.,	X	
	:	
Plaintiff,	:	
v.	:	
	:	Civil Action No. 04 CV 3627 (LTS)
GENERAL NUTRITION CENTERS, INC.,	:	
	:	
Defendant.	:	
	X	

**NOVOGEN RESEARCH PTY. LTD.'S REPLY TO DEFENDANT'S  
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Plaintiff Novogen Research Pty. Ltd. ("Novogen") by and through its undersigned counsel, as its reply to the counterclaims asserted by Defendant General Nutrition Centers, Inc. ("GNC"), states as follows:

**Counterclaim I – Declaratory Judgment  
of Non-Infringement of the '380 Patent**

1. Novogen admits to the allegations of Paragraph 1 of the Counterclaim.
2. Novogen admits the allegations of Paragraph 2 of the Counterclaim.
3. Novogen admits that this Court has subject matter jurisdiction over actions arising under 28 U.S.C. § 2201, et seq. and the patent laws of the United States. Novogen further admits that GNC purports to base jurisdiction for its counterclaims under this statutory section, but denies any liability arising thereunder.
4. Novogen admits that exclusive jurisdiction over the counterclaims is conferred upon the Court pursuant to 28 U.S.C. § 1338(a).

5. Novogen admits that it filed a First Amended Complaint against GNC alleging, *inter alia*, that certain products sold by GNC infringe certain claims of the '380 patent.

6. Novogen admits that an actual controversy now exists between the parties regarding GNC's infringement and the validity of the '380 patent because of Novogen's filing of its Complaint.

7. Novogen denies the allegations in Paragraph 7 of the Counterclaim.

#### **Counterclaim II – Invalidity of the '380 Patent**

8. Novogen hereby incorporates its responses to the allegations of Paragraphs 1 through 7 of the Counterclaim as if fully set forth in their entirety.

9. Novogen denies the allegations in Paragraph 9 of the Counterclaim. Further, Novogen avers that GNC has failed to plead any facts to support its allegation of invalidity. However, to the extent GNC will attempt to rely on allegations set forth in its Affirmative Defenses to support its Counterclaim, Novogen denies the allegations set forth in all eight of GNC's Affirmative Defenses.

10. Novogen denies the allegations in Paragraph 10 of the Counterclaim.

#### **AFFIRMATIVE DEFENSES**

##### **FIRST AFFIRMATIVE DEFENSE**

GNC's Counterclaims fail to state a claim upon which relief can be granted.

##### **SECOND AFFIRMATIVE DEFENSE**

GNC's Counterclaims are barred in whole or part by GNC's license with Solae, LLC.

**THIRD AFFIRMATIVE DEFENSE**

GNC's Counterclaims are barred in whole or part by the doctrine of equitable estoppel.

**FOURTH AFFIRMATIVE DEFENSE**

GNC's Counterclaims are barred in whole or part by the doctrine of waiver.


**FIFTH AFFIRMATIVE DEFENSE**

GNC's Counterclaims are barred in whole or part by the doctrine of laches.

**WHEREFORE**, Novogen Research Pty. Ltd. respectfully requests that:

- (a) GNC's Counterclaims be dismissed with prejudice; and
- (b) The Court grant the relief sought in Shire's First Amended Complaint.

Dated: New York, New York  
September 7, 2004

  
\_\_\_\_\_  
Porter F. Fleming (PF-1519)  
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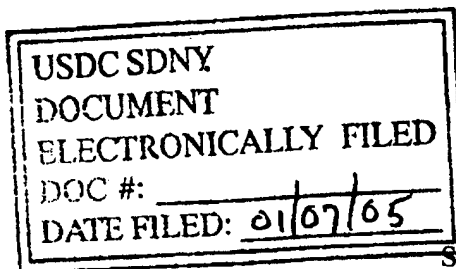
Attorneys for Plaintiff  
Novogen Research Pty. Ltd.

**CERTIFICATE OF SERVICE**

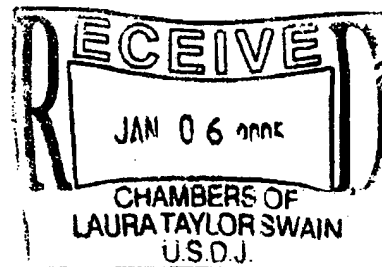
I hereby certify that on this 7th day of September 2004, a copy of the foregoing  
NOVOGEN RESEARCH PTY. LTD.'S REPLY TO DEFENDANT'S ANSWER,  
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS was served by facsimile and pre-paid  
first class mail on:

W. Joseph Melnik  
Raymond A. Miller  
PEPPER HAMILTON LLP  
500 Grant Street, 50<sup>th</sup> Floor  
Pittsburgh, PA 15219

Amanda Pellegrini



UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK



-----X  
NOVOGEN RESEARCH PTY. LTD., :

Plaintiff, :

v. :

GENERAL NUTRITION CENTERS, INC., :

Defendant. :  
-----X

Civil Action No. 04 CV 3627 (LTS) (DFE)

**CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION**

This action having been brought by Plaintiff Novogen Research Pty. Ltd. ("Plaintiff") against Defendant General Nutrition Centers, Inc., ("Defendant") for infringement of United States Patent No. 6,562,380 ("the '380 patent"); and

Plaintiff and Defendant, having reached the following agreements:

Defendant acknowledges that those claims of the '380 patent that require isoflavones derived from red clover and that relate to the treatment, reduction, prevention, or amelioration of the symptoms associated with pre-menstrual syndrome or menopause are valid and enforceable;

Defendant acknowledges that the manufacture, sale, and/or offer for sale of Defendants' GNC brand red clover containing products with claims to treat, reduce, prevent or ameliorate the symptoms associated with pre-menstrual syndrome or menopause or promoted for any of these purposes infringe the '380 patent;

Defendant reserves the right to challenge the validity, enforceability or infringement of the '380 patent with respect to (i) claims or products that do not require



or contain isoflavones derived from red clover or (ii) claims or products that are not promoted for the treatment, reduction, prevention or amelioration of the symptoms associated with pre-menstrual syndrome or menopause;

Plaintiff and Defendant have entered into an agreement providing for, *inter alia*, the settlement of this action and for a commercial arrangement between the parties ("Agreement").

Defendant and Plaintiff now consent to this Judgment and  
IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. This Court has jurisdiction over the parties and subject matter of this action.
2. The '380 patent is owned by Novogen Research Pty. Ltd., and those claims of the '380 patent that require isoflavones derived from red clover and relate to the treatment, reduction, prevention, or amelioration of the symptoms associated with pre-menstrual syndrome or menopause are valid and enforceable .
3. Defendant has infringed the claims of the '380 patent by manufacturing, selling, and/or offering to sell GNC brand red clover containing products with claims to treat, reduce, prevent or ameliorate the symptoms associated with pre-menstrual syndrome or menopause or promoted for any of these purposes.
4. Judgment on the basis of infringement by Defendant of the '380 patent as set forth above is entered in favor of Plaintiff.
5. Upon entry of this Judgment, Defendant shall be released of any claims for damages costs, attorney fees and interest as a result of Defendant's past infringement of the '380 patent, except as expressly provided in the Agreement.

6. All affirmative defenses pled or otherwise available to Defendant in this action are dismissed with prejudice, except as expressly provided in the Agreement.

7. All claims, which have been raised, and/or counterclaims, which have or could have been raised by Plaintiff and Defendant in this action are dismissed with prejudice, except expressly provided in the Agreement.

8. Absent prior authorization from Plaintiff, and except as set forth in the Agreement, Defendant, its officers, agents, servants, employees, affiliates, successors and all persons in active concert or participation with Defendant, are permanently enjoined from infringing the '380 patent during its term by using, promoting, offering for sale, importing, selling, shipping, distributing, or manufacturing in or to the United States and/or inducing others to use, promote, offer for sale, import, sell, ship, distribute or manufacture in the United States GNC brand red clover containing products with claims to treat, reduce, prevent or ameliorate the symptoms associated with pre-menstrual syndrome or menopause or promoted for any of these purposes.

9. Defendant is also hereby enjoined and estopped during the term of the '380 patent from making any challenge to the validity or enforceability of that patent to the extent the '380 patent is asserted against any GNC branded product that contains isoflavones derived from red clover and includes claims to treat, reduce, prevent or ameliorate the symptoms associates with pre-menstrual syndrome or menopause or promoted for any of these purposes.

10. The foregoing injunction against Defendant shall take effect immediately upon entry of this Judgment and Order by the Court, subject to the terms of the Agreement.

11. This Judgment is binding upon and constitutes *res judicata* between the parties in this action or in any other action in the United States relating to the '380 patent and GNC's branded red clover containing products with claims to treat, reduce, prevent or ameliorate the symptoms associated with pre-menstrual syndrome or menopause or promoted for any of these purposes.

12. The parties waive all right to appeal from this Judgment.

13. This Court shall retain jurisdiction of this action and over the parties for purposes of enforcement of the provisions of this Judgment.

14. Each party is to bear its own costs and attorney's fees.

Dated: New York, New York

January 5, 2005

FROMMER LAWRENCE & HAUG LLP

By: 

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Attorneys for Plaintiff  
Novogen Research Pty. Ltd.

PEPPER HAMILTON LLP

By: 

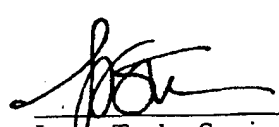
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New York, New York 10036

Attorneys for Defendant  
General Nutrition Centers, Inc.

SO ORDERED:

Dated: January 7, 2005

  
Laura Taylor Swain  
United States District Judge

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